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Patient-reported outcomes after simplification to a single tablet regimen of efavirenz (EFV)/emtricitabine (FTC)/tenofovir DF (TDF)

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Purpose of the study

To assess patient (pt) reported outcomes in AI266073, a 48-week, prospective, randomized, open-label, multicenter study.

Methods

Pts on stable antiretroviral therapy (ART) with HIV-1 RNA <200 c/mL for >3 months were randomized (2:1) to EFV/FTC/TDF (single tablet regimen) or to remain on their baseline regimen (SBR) and were stratified by prior PI- or NNRTI-based therapy. In addition to efficacy/safety, the following were collected from both study arms: adherence by visual analog scale, quality of life by SF-36(v2) survey, a 20-item self-reported HIV Symptoms Index, and the Perceived Ease of the Regimen for Condition questionnaire. In the EFV/FTC/TDF arm only, a protocol specific single-item Preference of Medication (POM) questionnaire was collected.

Summary of results

300 treated pts (EFV/FTC/TDF 203, SBR 97) were evaluated (prior PI/NNRTI 53%/47%); Through 48 weeks, 89% vs. 88% in the EFV/FTC/TDF vs. SBR arms, respectively, maintained HIV-1 RNA <200 c/mL by TLOVR (ITT; NC = F). Adherence in both arms at baseline and all visits was > 96%. Baseline SF-36 scores were similar to the general non-HIV infected population. There were no marked changes in adherence and SF-36 scores for either arm during the study. HIV Symptoms Index results demonstrated improvements in the proportion of pts randomized to EFV/FTC/TDF who experienced diarrhea or loose bowel movements (prior PI stratum: 52% at baseline; 32% at week 48 [p = 0.002]); bloating, pain, or gas in the stomach (p = 0.002); changes in the way their body looked (p = 0.002); and problems having sex (p = 0.032). There was a transient worsening of dizziness or lightheadedness symptoms (observed at week 4 only) in pts switched to EFV/FTC/TDF (p < 0.02), primarily in pts who switched from a PI-based regimen. Significantly more pts who received EFV/FTC/TDF considered it an easier regimen to take than their previous regimen (p < 0.001) at all study visits. By POM, pts randomized to EFV/FTC/TDF preferred this treatment over their previous regimen (p < 0.001) at all post-baseline visits; 85% reported at week 48 that EFV/FTC/TDF was "much better" than their previous regimen.

Conclusion

Simplification to EFV/FTC/TDF from a variety of ART maintained high levels of virologic suppression, adherence and quality of life through 48 weeks. Pts switched to EFV/FTC/TDF reported improvements in many HIV-related symptoms, found the new regimen easier to follow and preferred EFV/FTC/TDF over their previous ART regimen.